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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,705	06/25/2003	Kent Harrison	10527-454001	3440
26161	7590	09/19/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			JOHNSON III, HENRY M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/603,705	Applicant(s) HARRISON, KENT	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,14-24 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,19-22,37 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-11,14-18,23,24,35,36,38-41 and 43-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>090506</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed September 9, 2005 have been fully considered but they are not persuasive. Swanson clearly teaches an introducer with the catheter, the introducer being a sleeve. Swanson teaches methods for accessing a heart using vascular entry that are well known in the art and common for ablation, mapping, pacing, etc. While Swanson's device is directed towards cryoablation, the element clearly cools in the process. Boyd et al. teaches cooling of the heart using thorax access techniques. One of skill in the art would know the difference, benefits and limitations of both cryoablation and controlled cooling of cardiac tissue. A skilled artisan would be cognizant of these and other devices and methods using in such cardiac treatment and have strong motivation to use the least traumatic and most beneficial devices and methodologies.

Applicant's request to consider withdrawn claims is denied as the claims from which they depend remain rejected.

During examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).

A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Yanush, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); Ex parte Masham, 2 USPQ2d 1647 (BdPatApp & Inter 1987).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent Application Publication US 2004/0215177 to Swanson. Swanson discloses catheter-based probes with a relatively long and flexible catheter body that supports a cryogenic element at or near its distal end. The catheter is interpreted as an elongate shaft and a cryogenic element is clearly a cooling structure. The portion of the catheter body that is inserted into the patient is typically from 60 to 140 cm in length and there may be another 20 to 40 cm, including a handle, outside the patient. The length and flexibility of the catheter body allow the catheter to be inserted into a main vein or artery (typically the femoral vein) and directed into the interior of the heart such that the cryogenic element contacts the tissue that is to be ablated (paragraph 0040). Swanson discloses an introducer sheath to introduce a catheter and surgical probes into the body. The introducer sheath has a relatively long body that may extend through the insertion area to the target tissue region (paragraph 0042). The introducer is interpreted as an elongate sleeve and is clearly sized to be used with a blood vessel. Swanson teaches the cooling may be a cryogenic element, such as a balloon or hollow metal tip, is carried on the distal end of a catheter or surgical probe placed in contact with tissue and cooled. The cryogenic element may be cooled by directing super-cooled fluid through the catheter or

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surgical probe to the cryogenic element (paragraph 0005). Swanson discloses a catheter with infusion and ventilation lumens that may be used for delivery of cooling medium (paragraph 0047). As the catheter is introduced, the tip would inherently be deployed from the end of the introducer sleeve.

Claims 1, 3-4, 7-11, 14-18 and 44-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent 5,799,661 to Boyd et al. Boyd et al. teach devices and methods for cardiac surgery including a device for cooling tissue comprising an elongate shaft

(Fig. 42, # 233) with a deployable cooling structure at its distal end (Fig. 42, # 231), delivered to the treatment site via a sheath (Fig. 42,

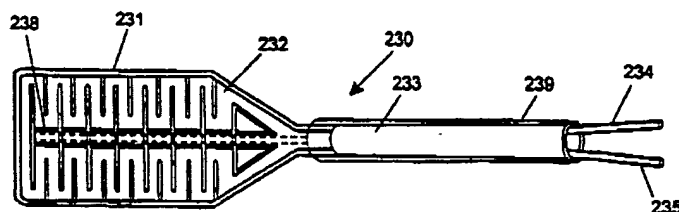


FIG.42

239). The sheath is retracted to deploy the cooling structure, this movement interpreted as deploying the cooling structure in a longitudinal direction. The flexible heat exchanger (231) is collapsible to a pre-deployed position that can easily fit through an access port. The orifice into which it is inserted has no impact on the device structure rendering it irrelevant in a device claim. The flexible heat exchanger is attached to the distal end of an elongated tubular shaft (233). An inflow lumen (234) extends through the tubular shaft and is fluidly connected to the flexible heat exchanger. A return lumen (235) extends through the tubular shaft parallel to the inflow lumen. The lumens may be formed integrally with the tubular shaft. The proximal ends of the inflow lumen and the return lumen are adapted for attachment to a circulating pump and a reservoir of cooling fluid (Col. 21, lines 5-25). The flexible heat exchanger is interpreted as a patch and the shaft is longitudinally movable with the sheath. The flexible heat exchanger is made from two sheets of flexible plastic which are heat sealed or RF sealed together to form a serpentine cooling path (232) through the heat exchanger. Preferred materials for

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manufacturing the flexible heat exchanger 231 include polyurethane, vinyl, polypropylene, nylon, etc. The flexible heat exchanger may have a flexible backbone (frame) that extends from the distal end of the tubular shaft to the distal edge of the heat exchanger. The flexible backbone may be made from a flexible polymer, elastomer, or a resilient metal wire, such as spring temper stainless steel or a superelastic nickel/titanium alloy, or a composite of metal and plastic. The flexible heat exchanger is rolled, folded or twisted and placed in an introducer sheath 239 in the pre-deployed position (Col. 21, lines 25-41).

Regarding claims 7-8 and 14-15, these relate to intended use, however, the structure of Boyd et al. is capable of meeting the claim limitation.

Except for the disclosed size, Boyd et al. clearly anticipate the structure of the claims. A skilled artisan would be motivated to look to Boyd et al. for a cooling device as the trend in the art is toward less invasive cardiac procedures, such as intravascular introduction of devices using introducer sleeves and catheters. A change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

Regarding claim 18, Boyd et al. disclose the claimed invention except for dual patches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an additional patch, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35, 36, 38, 39, 40, 41, 43, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0215177 to Swanson in view of U.S. Patent 5,799,661 to Boyd et al. Both have been previously discussed. Swanson teaches methods for positioning and deploying a cryogenic element within a heart, but not cooling without ablation. Boyd et al. teach a device and method for cooling without ablation of a heart by cooling the outside surface with a cooling patch. One of skill in the art would be motivated to use a smaller cooling device as taught by Boyd et al. in the vascular access methodology as of Swanson to provide a less traumatic invasion to cool the heart.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,799,661 to Boyd et al. in view of U.S. Patent 6,514,245 to Williams et al. Boyd et al. are discussed above, but do not teach the use of gas expansion or the Joule-Thompson effect for cooling. Williams et al. disclose a cryotherapy catheter where the cooling fluid may pass through a Joule-Thompson orifice (Col. 14, lines 44-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a Joule-Thompson orifice as taught by Williams et al. in the device of Boyd et al. because it is a well known methodology for cooling in medical devices. Those skilled in the art would look to related inventions in the cryotherapy for structures and methodologies for implementation, providing the motivation for such a combination.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,799,661 to Boyd et al. in view of U.S. Patent Application Publication US 2004.0030259 to Dae et al. Boyd et al. are discussed above, but do not teach a temperature sensor near the heat exchange area. Temperature sensors are well known and pervasive in the art as evidenced by the sensor of Dae et al. (abstract). It would have been obvious to one having ordinary skill in

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the art at the time the invention was made to use a temperature sensor as taught by Dae et al. in the device of Swanson in view of Boyd et al. to monitor the process of cooling.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
Art Unit 3739